

aortic stenosis with a mean AV effective orifice area of 1.9 ± 0.5 cm² and 1.9 ± 0.4 cm²; and gradient of 8.1 ± 3.3 mmHg and 7.6 ± 3.1 mmHg, at 30 days and 6 months, respectively. Compared with baseline, 76.3% of patients experienced improvement in NYHA class at 30 days, and 84.9% at 6 months. Permanent pacemaker rates were 11.7% at 30 days, and 13.4% at 6 months.

CONCLUSIONS The Evolut R TAV is associated with exceptional safety at 30 days, which continued at 6 months. We plan to report 1-year outcomes at the time of the meeting.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Outcomes, TAVI

TAVR II

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Valve thrombosis after transcatheter aortic valve replacement: incidence, characteristics and outcomes

John Jose Erungaren,¹ Dmitriy S. Sulimov,¹ Mohamed El-Mawardy,¹ Takao Sato,¹ Abdelhakim Allali,¹ Martin Landt,² Bettina Schwarz,³ Gert Richardt,¹ Mohamed Abdel-Wahab¹

¹Heart Center, Segeberger Kliniken, Bad Segeberg, Germany; ²Heart Center, Segeberger Kliniken, Bad Segeberg, Germany; ³Heart Center Segeberger Kliniken, Bad Segeberg, Germany

BACKGROUND Data on transcatheter aortic valve replacement (TAVR) failure is limited. The study objective was to determine the incidence, timing, clinical characteristics and treatment outcomes of patients diagnosed with TAVR failure attributed to transcatheter heart valve (THV) thrombosis.

METHODS A retrospective analysis of prospectively raised data included in a single center TAVR registry. Patients in this 100% follow-up registry have a predefined echocardiographic and clinical follow-up schedule (1 month, 6 months, 1 year and yearly thereafter or earlier if symptomatic). THV thrombosis was defined as (1) valve dysfunction (mean transvalvular gradient >20 mmHg, reduction of the aortic valve area to <1.2 cm² or new onset more than mild transvalvular regurgitation) secondary to thrombosis diagnosed based on response to anticoagulation therapy or typical findings on imaging modality (Echo/CT) or (2) mobile mass suspicious of thrombus detected on the valve, irrespective of dysfunction, and in the absence of infection. The primary study endpoint was the incidence of THV thrombosis.

RESULTS During the study period (September 2007-March 2015), 588 patients underwent TAVR (CoreValve-305, Sapien XT-124, Sapien 3-117, Lotus-40, others-2). THV thrombosis was diagnosed in 12(2%) patients: Sapien XT-9, Sapien 3-1 and Lotus-2. Thrombosis was not observed in any of the CoreValve patients. The mean age was 79 ± 8 years and the majority were females ($n=10$, 83.3%). The median time to thrombosis detection was 180 days (interquartile range, IQR 23-472). 3 patients were diagnosed early (within 1 month) after TAVR, of which 2 had a Lotus valve. In another 3 patients, thrombosis was diagnosed late (>1 year after TAVR). Half of the patients had no worsening symptoms at the time of diagnosis. In symptomatic subjects, exertional dyspnea with change in NYHA class was the most common mode of presentation ($n=5$). 1 patient presented with stroke. Treatment at the time of detection of thrombosis was dual antiplatelet therapy in 11 and aspirin monotherapy in 1. No cases of THV thrombosis were seen in patients discharged on oral anticoagulation. Mean aortic valve pressure gradient was elevated in 10(83%) of thrombosis patients; mean transvalvular gradient for all subjects being 36 ± 16 mmHg. Other echocardiographic findings included thrombotic mass on the leaflets ($n=7$, 58.3%) and thickening of leaflets with reduced mobility. Median serum NT-proBNP level was 1318 pg/ml (IQR 1123-1605). After treatment with anticoagulants, mean aortic gradient and NT-proBNP levels reduced significantly. There were no deaths related to valve thrombosis.

CONCLUSIONS THV thrombosis is a rare but an important cause of TAVR failure, most frequently detected at a median of 180 days after the procedure. Patients may present with exertional dyspnea and/or

increased transvalvular gradients. Anticoagulation is effective in improving gradients and clinical status. Optimal antithrombotic therapies after TAVR need to be defined, and randomized controlled trials are needed.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, Thrombosis, Transcatheter aortic valve replacement

TCT-100

Transcatheter Aortic Valve Replacement in Patients With End-Stage Renal Disease: One Year Outcomes from the CoreValve US Expanded Use Study

Daniel O'Hair,¹ George Petrossian,² Tanvir Bajwa,³ Stanley J. Chetcuti,⁴ G Michael Deeb,⁴ Neal Kleiman,⁵ Michael J. Reardon⁶

¹Aurora St. Luke's Medical Center, Milwaukee, WI; ²St. Francis Hospital, Roslyn, NY; ³ACS, Aurora Sinai/St. Luke's Med Ctrs, Univ Wisconsin School of Medicine and Public Health, Milwaukee, WI; ⁴University of Michigan, Ann Arbor, MI; ⁵Houston Methodist DeBakey Heart and Vascular Center, Houston, United States; ⁶Houston Methodist DeBakey Heart & Vascular Center, Houston, TX

BACKGROUND End stage renal disease (ESRD) poses unique challenges in the treatment of patients with severe aortic stenosis. While surgical valve replacement in patients with ESRD has been associated with an increase in the risk of morbidity and mortality, the results from transcatheter valve replacement have not been clearly defined.

METHODS The CoreValve US Expanded Use Study is a prospective, nonrandomized trial of transcatheter aortic valve replacement (TAVR) in extreme risk (ER) patients with ESRD or other specific comorbidities excluding them from the Pivotal Trial. Patients with ESRD who were deemed to be ER by two surgeons, had symptoms attributable to aortic stenosis, had an aortic valve area of ≤ 0.8 cm² (or aortic valve area index ≤ 0.5 cm²), and either a mean gradient ≥ 40 mmHg or peak velocity ≥ 4.0 m/s with one year of follow up are included in this report. The primary endpoint for the study was all-cause mortality or major stroke at 12 months. One year outcomes are compared with patients enrolled in the CoreValve ER US Pivotal Trial and an objective performance goal (OPG) pre-specified for the ER US Pivotal Trial.

RESULTS Fifty-four patients with ESRD underwent TAVR with CoreValve as part of the US Expanded Use Study and have reached one year follow up. Mean STS-PROM was 17.1 ± 8.4 in ESRD patients versus 10.3 ± 5.5 in ER US Pivotal patients. The rate of all-cause mortality or major stroke at 12 months was 26% in the ER US Pivotal Trial, 35% in the ESRD Expanded Use Study, and compared with 43% which is the ER US Pivotal Objective Performance Goal. Initial 30 day all-cause mortality was 7.4% (8.4 % in US Pivotal) and 1 year was 35.2% in ESRD patients. Any stroke or TIA at 1 year was 1.9%, major vascular injury was 3.7% and new permanent pacemaker rate was 22.9%. Valve performance at one year was comparable to post-procedure in effective orifice area (1.82 cm² post-procedure v. 1.81 cm² 1 year) and mean gradient (9.8 mmHg post-procedure v. 9.2 mmHg 1 year).

CONCLUSIONS Early mortality in patients with ESRD is comparable to ER patients without ESRD but one year data suggest a higher mortality likely due to comorbid conditions. Stroke and major vascular injury were infrequent and valve durability is maintained at one year.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic valve stenosis, Renal failure, end-stage, Transcatheter aortic valve replacement

TCT-101

Experience with cerebral protection during transcatheter aortic valve replacement: the ALSTER registry

Tobias Schmidt,¹ Ulrich Schäfer,² Ozan Akdag,³ Oscar D. Sanchez,⁴ Elena Ladich,⁵ Thielsen Thomas,⁶ Michael Schlüter,⁷ Dimitry Schewel,⁸ Jury Schewel,⁹ Felix Kreidel,⁸ Hannes Alessandrini,¹⁰ Karl-Heinz Kuck,¹¹ Christian Frerker⁸

¹Asklepios Klinik St. Georg, Hamburg, Hamburg; ²Department of Cardiology, Asklepios Klinik St. Georg, Hamburg, Germany, Hamburg, Germany; ³Asklepios Klinik St. Georg, Hamburg, OH; ⁴CVPath, Gaithersburg, MD; ⁵CV Path, Gaithersburg, USA; ⁶Department of Cardiology, Asklepios Klinik St. Georg, Hamburg, Germany, Hamburg, Germany; ⁷Asklepios proresearch, Hamburg, Germany; ⁸Asklepios Clinic St. Georg, Hamburg, Hamburg; ⁹Asklepios Klinik St. Georg - University of Hamburg, Hamburg, Germany; ¹⁰Asklepios Klinik St. Georg, Hamburg, Germany; ¹¹Cardiology, Hamburg, Germany

BACKGROUND A peri-procedural stroke rate of 2-7% remains a major complication after transcatheter aortic valve replacement (TAVR) and